

U.S.S.N.: 09/766,362

Filed: January 19, 2001

AMENDMENT AND RESPONSE TO OFFICE ACTION

APPENDIX II: Clean Copy of Claims as Pending

1. (Twice amended) A composition for the nasal administration of a drug in a dry powder form having an average particle size of between 10 and 20 microns, in a dosage formulation suitable for administration to the nasal region,

the dry powder form comprising microparticles which comprise the drug and a material selected from the group consisting of diketopiperazines, poly(hydroxy acids), poly(lactic acid), poly(glycolic acid) and copolymers thereof, polyanhydrides, polyesters, polyorthoesters, polyamides, polycarbonates, polyalkylenes including polyethylene and polypropylene, poly(ethylene glycol), poly(ethylene oxide), poly(ethylene terephthalate), polyvinyl alcohols, polyvinyl ethers, polyvinyl esters, polyvinyl halides, polyvinylpyrrolidone, poly vinyl chloride, polystyrene, polysiloxanes, polymers of acrylic and methacrylic acids including poly(methyl methacrylate), poly(ethyl methacrylate), poly(butylmethacrylate), poly(isobutyl methacrylate), poly(hexylmethacrylate), poly(isodecyl methacrylate), poly(lauryl methacrylate), poly(phenyl methacrylate), poly(methyl acrylate), poly(isopropyl acrylate), poly(isobutyl acrylate), poly(octadecyl acrylate), polyurethanes and co-polymers thereof, celluloses including alkyl cellulose, hydroxyalkyl celluloses, cellulose ethers, cellulose esters, nitro celluloses, methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxy-propyl methyl cellulose, hydroxybutyl methyl cellulose, cellulose acetate, cellulose propionate, cellulose acetate butyrate, cellulose acetate phthalate, carboxylethyl cellulose, cellulose triacetate, and cellulose sulphate sodium salt, poly(butic acid), poly(valeric acid), poly(lactide-co-caprolactone), zein, prolamines and hydrophobic proteins, copolymers and mixtures thereof.

2. The composition of claim 1 wherein the drug is selected from the group consisting of antihistamine, vasoconstrictors, antiinflammatories and analgesics.

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3. The composition of claim 2 wherein the antihistamine is selected from the group consisting of chlorpheniramine and azelastine.

4. The composition of claim 1 wherein the drug is formulated in a polymeric carrier.

5. The composition of claim 1 wherein the drug is formulated in a diketopiperazine formulation.

6. The composition of claim 1 wherein the dry powder formulation consists essentially of drug.

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7. (Twice amended) A drug delivery device for nasal administration comprising a drug in a dry powder form having an average particle size of between 10 and 20 microns, in a dosage formulation for administration to the nasal region, and a device for delivering a measured dose of the drug to the nasal mucosa, wherein the dry powder form comprises microparticles which comprise the drug and a material selected from the group consisting of diketopiperazines, poly(hydroxy acids), poly(lactic acid), poly(glycolic acid) and copolymers thereof, polyanhydrides, polyesters, polyorthoesters, polyamides, polycarbonates, polyalkylenes including polyethylene and polypropylene, poly(ethylene glycol), poly(ethylene oxide), poly(ethylene terephthalate), polyvinyl alcohols, polyvinyl ethers, polyvinyl esters, polyvinyl halides, polyvinylpyrrolidone, poly vinyl chloride, polystyrene, polysiloxanes, polymers of acrylic and methacrylic acids including poly(methyl methacrylate), poly(ethyl methacrylate), poly(butylmethacrylate), poly(isobutyl methacrylate), poly(hexylmethacrylate), poly(isodecyl methacrylate), poly(lauryl methacrylate), poly(phenyl methacrylate), poly(methyl acrylate), poly(isopropyl acrylate), poly(isobutyl acrylate), poly(octadecyl acrylate), polyurethanes and co-polymers thereof, celluloses including alkyl cellulose, hydroxyalkyl celluloses, cellulose ethers, cellulose esters,

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nitro celluloses, methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxy-propyl methyl cellulose, hydroxybutyl methyl cellulose, cellulose acetate, cellulose propionate, cellulose acetate butyrate, cellulose acetate phthalate, carboxylethyl cellulose, cellulose triacetate, and cellulose sulphate sodium salt, poly(butic acid), poly(valeric acid), poly(lactide-co-caprolactone), zein, prolamines and hydrophobic proteins, copolymers and mixtures thereof.

8. The device of claim 7 wherein the device is a nasal insufflator.

9. The device of claim 7 wherein the drug is selected from the group consisting of antihistamine, vasoconstrictors, antiinflammatories and analgesics:

10. The device of claim 7 wherein the antihistamine is selected from the group consisting of chlorpheniramine and azelastine.

11. The device of claim 7 wherein the drug is formulated in a polymeric carrier.

12. The device of claim 7 wherein the drug is formulated in a diketopiperazine formulation.

13. The device of claim 7 wherein the dry powder formulation consists essentially of drug.

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14. (Twice amended) A method of administering a drug to the nasal region of a patient in need thereof, comprising nasally administering a dry powder form of a drug having an average particle size of between 10 and 20 microns, in a dosage formulation suitable for nasal administration,

wherein the dry powder form comprises microparticles which comprise the drug and a material selected from the group consisting of diketopiperazines, poly(hydroxy acids), poly(lactic acid), poly(glycolic acid) and copolymers thereof, polyanhydrides, polyesters, polyorthoesters, polyamides, polycarbonates, polyalkylenes including polyethylene and

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polypropylene, poly(ethylene glycol), poly(ethylene oxide), poly(ethylene terephthalate), polyvinyl alcohols, polyvinyl ethers, polyvinyl esters, polyvinyl halides, polyvinylpyrrolidone, poly vinyl chloride, polystyrene, polysiloxanes, polymers of acrylic and methacrylic acids including poly(methyl methacrylate), poly(ethyl methacrylate), poly(butylmethacrylate), poly(isobutyl methacrylate), poly(hexylmethacrylate), poly(isodecyl methacrylate), poly(lauryl methacrylate), poly(phenyl methacrylate), poly(methyl acrylate), poly(isopropyl acrylate), poly(isobutyl-acrylate), poly(octadecyl acrylate), polyurethanes and co-polymers thereof, celluloses including alkyl cellulose, hydroxyalkyl celluloses, cellulose ethers, cellulose esters, nitro celluloses, methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxy-propyl methyl cellulose, hydroxybutyl methyl cellulose, cellulose acetate, cellulose propionate, cellulose acetate butyrate, cellulose acetate phthalate, carboxylethyl cellulose, cellulose triacetate, and cellulose sulphate sodium salt, poly(butic acid), poly(valeric acid), poly(lactide-co-caprolactone), zein, prolamines and hydrophobic proteins, copolymers and mixtures thereof.

15. The method of claim 14 wherein the drug is selected from the group consisting of antihistamine, vasoconstrictors, antiinflammatories and analgesics.
16. The method of claim 14 wherein the antihistamine is selected from the group consisting of chlorpheniramine and azelastine.
17. The method of claim 14 wherein the drug is formulated in a polymeric carrier.
18. The method of claim 14 wherein the drug is formulated in a diketopiperazine formulation.
19. The method of claim 14 wherein the dry powder formulation consists essentially of drug.

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